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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/614,790	07/12/2000	Sharon F. Kleyne	HME/7982.001	2570
29085	7590	03/17/2005		
HOWARD EISENBERG, ESQ. 2206 APPLEWOOD COURT PERKASIE, PA 18944			EXAMINER WANG, SHENGJUN	
			ART UNIT 1617	PAPER NUMBER
DATE MAILED: 03/17/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/614,790	<b>Applicant(s)</b> KLEYNE, SHARON F.	
	<b>Examiner</b> Shengjun Wang	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2004.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 75-96 is/are pending in the application.  
4a) Of the above claim(s) 94-96 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 75-93 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

Receipt of applicants' amendments and remarks submitted December 9, 2004 is acknowledged.

#### ***Restriction***

1. Newly submitted claims 94-96 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:
2. Inventions of claims 94-96 and claims 75-93 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process as claimed could be practiced with another materially different product such as using eye drop or mist generated from a humidifier.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 94-96 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

#### ***Claim Rejections 35 U.S.C. 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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2. Claims 75-89 are rejected under 35 U.S.C. 102(b) as being anticipated by a practice has been doing by many people, i.e., be in a mist environment, such as walking in a foggy morning, take a sauna bath. The claimed invention is directed to a method of moisturizing eye by contacting the surface of eye with less than 3 microliter (claims 75-82) or less than 10 microliter (claims 83-89). Any person step in a mist environment will subject his eyes to contact with the water mist. However, the amount of water absorbed on eye surface is not likely to exceed 3 microliter since the mist is not particularly directed to the eyes. Note, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claims are interpreted broadly as read on contact the eyes with mist. As to the functional limitation recited in claims 83 and 86, note, the functional limitation fails to distinguish the claimed method, since the ultimate steps in the method, i.e., contact eyes with mist, are not affected by such limitations. Further, note the size of droplets in mist is in the range of 2 to 100 micrometers. See "Selected terms in colloid and interface science Aerosols."

***Claim Rejections 35 U.S.C. 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 75-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Embleton et al (WO 97/23177) in view of Laibovitz et al (US Pat. 5,997,518).

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Embleton teaches the advantages of administering smaller volumes of ophthalmic solutions to the eye. The tear volume can increase to about 30 microliters before overflowing occurs and the excess fluid is lost (see page 1, lines 5-23). Embleton also teaches that ocular bioavailability is enhanced by delivery to the eye in the form of a jet or stream of droplets (see page 2). As a general guide, Embleton teaches that droplet diameters in the range of 20 to 1000 microns are suitable, and that total volume should not exceed 20 microliters (see page 3, Lines 1-37). Ophthalmic treatment liquids may be aqueous, and optionally contain a therapeutic compound (see page 12, lines 6-9). Specifically named fluids include water, optionally containing polymeric compounds (see page 13, Lines 7-12). It is the position of the examiner that the optional ingredients are not required in the ophthalmic treatment liquids, and that Embleton specifically teaches the use of water as an ophthalmic treatment liquid.

While the reference teaches the use of droplets with diameters generally in the range of 20-1000 microns and total volumes less than 20 microliters, the reference lacks teaching droplet diameter specifically in the 10-20 micron range and volumes in the 1-3 microliter range.

Laibovitz teaches a device and method for delivering small microliter volumes of liquid preparations to the eye. Laibovitz teaches that the ability of a system to deliver small volumes of a liquid as droplets is of particular interest. The size of the drop is as found in an aerosol or mist, in the 1-5 micron range (see col. 3, Lines 11-27). Laibovitz teaches that the smaller volumes are especially designed to remain within the capacity of the eye to hold the solutions (see col. 3, Lines 35-40). The apparatus as taught by Laibovitz delivers small volumes between 1 and 25 microliters (see col. 5, lines 8-14). Tables 1 and 2 show delivery of 2 microliters of fluid by the device as taught by Laibovitz (see col. 13, Line 19 through col. 15, line 40).

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It would have been obvious to one of ordinary skill at the time the invention was made to have modified the administration of compositions as taught by Embleton by the use of the methods and apparatus as taught by Laibovitz in order to avoid overflowing the capacity of the tear film and subsequent loss of the administered fluid.

As to the functional limitation recited in claims 83 and 86, note, the functional limitation fails to distinguish the claimed method, since the ultimate steps in the method, i.e., contact eyes with mist, are not affected by such limitations.

3. Claims 90-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Junkel et al. (US 5,620,633).

4. Junkel et al. teaches a potable misting device for sunbathers and others involved in athletic pursuits, which provide a cooling current air with atomized liquid mist, such as water, to combat the elements of heat and dehydration attendant with athletic activities and/or prolonged exposure to the sun. Junkel et al. further disclosed that such type of devices are well-known in the art. See, particularly, the abstract, and column 1, lines 18-63. The device comprises a sealed container, water within the container, and an actuator for spraying a mist of water from the container, See, particularly, the drawing, and columns 4, line 60 bridging to column 5, line 10.

5. Junkel et al. do not teach expressly to apply the mist to the face of a subject, or the subject is suffering from dry eye.

However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to direct the fan-mist device to the face, and apply the mist accordingly and enjoy the relief of the dryness, including the dry eye condition, caused by heat and dehydration. As to claim 92, which recites the particular condition of protein

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and electrolytes, it is noted the mist generated by the device of Junkel is not likely to wash away those protein and electrolyte since the water is in the form of mist, not a stream. Further, the employment of pressurizing agent in a mist generating device instead of hand generated pressure as disclosed by Junkel et al. is seen to be an obvious variation and is within the skill of artisan.

### ***Response to the Arguments***

Applicants' amendments and remarks submitted December 9, 2004 have been fully considered, but are not persuasive.

The examiner disagrees with applicants definition of "administering a fluid" or "applying a fluid." A person steps in a mist is an action. By taking this step, the person effectively administering a mist to his eyes.

6. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the teaching, suggestion and motivation are found both in the cited references, and in the knowledge generally available to one of ordinary skill in the art.

7. Applicants again argue the mutual exclusiveness of "mist" recited in claims 79 and 88 and "jet stream of droplets" recited by Embleton. Applicants erred in interpreting the term to narrow. "jet stream of droplets" is not a single line of droplets, but a stream of droplet mass, or a stream of mist. Further, even give "jet stream of droplets" the narrow interpretation; the

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combination of the references would have made the claimed invention prima facie obvious. Particularly, the employment of “jet stream of droplets” in Embleton is for accurately delivery, Laibovitz teaches the particular device which is able to deliver a desirable small amount of liquid to the eyes accurately and conveniently. It would have been obvious for one of ordinary skill in the art to employ the device disclosed by Laibovitz et al. with reasonable expectation to enjoy the accuracy and convenience. Further, in view of the nature of the problem to be solved by the claimed invention, i.e., moisturizing dry eyes, it would have been obvious to one of ordinary skill in the art, to employ a composition consisting essentially of water for moisturizing eyes, as suggested by Embleton et al.

Regarding Embleton’s teaching, note, Embleton’s teaching encompass using water without other additives. Question under 35 U.S.C. 103 is not merely what reference expressly teach, but what they would have suggested to one of ordinary skill in the art at the time the invention was made; all disclosures of prior art, including unpreferred embodiments, must be considered. In re Lamberti and Konort (CCPA), 192 USPQ 278.

Applicants assert commercial success as objective evidence of nonobviousness. To establish objective evidence of nonobviousness based on commercial success, a few notable principles are well settled. An applicant who is asserting commercial success to support its contention of nonobviousness bears the burden of proof of establishing a nexus between the claimed invention and evidence of commercial success. The Federal Circuit has acknowledged that applicant bears the burden of establishing nexus, stating:

In the ex parte process of examining a patent application, however, the PTO lacks the means or resources to gather evidence, which supports or refutes the applicant's assertion that the



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sale constitutes commercial success. C.f. Ex parte Remark, 15 USPQ2d 1498, 1503 (Bd. Pat. App. & Int. 1990)(evidentiary routine of shifting burdens in civil proceedings inappropriate in ex parte prosecution proceedings because examiner has no available means for adducing evidence). Consequently, the PTO must rely upon the applicant to provide hard evidence of commercial success.

Further, objective evidence of nonobviousness including commercial success must be commensurate in scope with the claims. In re Tiffin, 448 F.2d 791, 171 USPQ 294 (CCPA 1971).

Objective evidence which must be factually supported by an appropriate affidavit or declaration to be of probative value includes evidence of unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. See MPEP 716.01 to 716.03 for the detailed requirement for establish commercial success as objective evidence of nonobviousness.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1617